K100154

MAY 21 2010

510(k) SUMMARY

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Date Prepared:	January 15, 2010 (revised April 21, 2010)

DEVICE NAME

Trade/Proprietary Name:	Fixcet™ Spinal Facet Screw System
Classification Name:	System, Facet Screw Spinal Device
Common Name:	Facet Screw

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified facet screw spinal devices as Unclassified. The product code for System, Facet Screw Spinal Device is MRW. These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The X-spine Systems, Inc. Fixcet Spinal Facet Screw system is intended for posterior fixation to the lumbar spine (L1 to S1 inclusive). The system is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion. The system is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

- Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies),
- Degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm,
- Trauma (i.e., fractures and/or dislocations),
- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis and/or failed previous fusions.

DEVICE DESCRIPTION

The X-spine Fixcet Spinal Facet Screw System is designed to provide bilateral, transfacet fixation of the spinal facet joint in the lumbar spine. This system consists of titanium alloy bone screws designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. The self-tapping 4.5mm diameter facet screws are available in two configurations: (1) single-threaded screws offered in lengths of 25-45mm (in 5 mm increments); and (2) dual-threaded screws offered in lengths of 30-45mm (in 5 mm increments). The screws are composed of medical grade Titanium alloy (Ti6Al4V) that complies with ASTM F-136.

The implant components are provided clean and non-sterile. These devices are sterilized by a healthcare professional using Steam Autoclave in accordance to the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the manufacturer of the Autoclave.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Fixcet Spinal Facet Screw system is substantially equivalent to the Depuy Spine Discovery System (K012773) and the SpineFrontier Chameleon System (K071420) based on a comparison of the following:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Levels of Fixation
- Implant Materials
- Product Dimensions
- Mechanical Performance

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F2193 – *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*

- Static Compression Bending
- Fatigue Compression Bending

ASTM F543 – *Standard Specification and Test Methods for Metallic Medical Bone Screws*

- Torsional Yield Strength
- Insertion Torque
- Removal Torque
- Pullout Force
- Self-Tapping Performance

In conclusion, biomechanical testing results indicate that the Fixcet Spinal Facet Screw System is substantially equivalent to predicate device performance and is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2010

X-Spine Systems, Inc.
% David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K100154
Trade/Device Name: Fixcet™ Spinal Facet Screw System
Regulation Number: Unclassified
Product Code: MRW
Dated: April 21, 2010
Received: May 19, 2010

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100154

Indications for Use

510(k) Number (if known): **K100154**

Device Name: Fixcet™ Spinal Facet Screw System

Indications for Use:
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- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis and/or failed previous fusions.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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